2. 510(k) Summary

Submitter: Redsense Medical AB
Rörkullsvägen 4
Box 287
301 07 HALMSTAD
SWEDEN

OCT 18 2007

Contact Information: Constance G. Bundy
6470 Riverview Terrace
Fridley, MN 55432

Submission Date:

Device Name and Classification: Redsense, Class II, 876.5540, product code not known

Equivalent Device Identification: Neotrend (K972314) and Fresenius 2008 Touch panel control Dialysis system (K890824)

Device Description: Redsense is a system for monitoring the vein or arterial needle during hemodialysis. Redsense consists of an alarm unit and infrared sensor incorporated into an adhesive patch. The patch with the sensor is placed around the vein or arterial needle and detects any blood that drips onto the patch if the needle has been accidentally pulled out or if there is leakage during dialysis. If blood loss is detected, the device will alarm.

Intended Use: The Redsense device is intended to monitor for potential blood loss from the hemodialysis access site in hemodialysis patients undergoing continuous hemodialysis treatment up to 5 hours in the clinical setting. The device includes a blood sensor incorporated into an adhesive sensor patch. The sensor monitors potential blood leakage from the venous needle puncture site via an infrared light and will alarm if blood leakage is detected via absorption onto the device's sensor patch.

Comparison Table

Parameter	Proposed Device	Predicate device 1	Predicate Device 2
Device	Redsense	Neotrend Multiparameter Sensor	Vein pressure supervision, integrated in Fresenius 2008 Dialysis system
Intended Use	Monitor blood leakage from venous needle puncture site	Continuous blood gas monitoring system for pO_2, temperature, pCO_2 and pH	Blood line separation (can be caused by vein needle dislodgement)
Manufacturer	Redsense Medical	Diametrics Medical ltd	Fresenius
Technology	Blood detection through IR light absorption in fiber optics/ adhesive absorption pad	Blood gas sensor thought optical fiber/ fluorescence quenching technology (fiber optic photometric absorption)	Pressure detection
Blood amount for detection	approximately 2 ml	Not specified	Not specified, alarm pressure level can be adjusted
Area of detection	NA "Blood or no blood"	pO_2 20-500mmHg, temperature 10-42 °C, pCO_2 10-160 mmHg and pH 6.80 - 7.80	-60 to 520 mmHG
Tolerance	NA	pO_2 +/- 3mmHg, temperature +/- 0,3 °C, pCO_2 +/- 3 mmHg and pH +/- 0.03	+/- 10 mmHg
Size of sensor	D= 0.25 mm	D= 0.5 mm	
Optical Fiber type	Plastic	Plastic	NA
Light type	Infrared	Green and Red visible	NA
Components parts	Fibre Optical blood detector, adhesive, absorbent	Fiber Optical blood sensor with chemical dye	Pressure sensor
Single use	Yes	Yes	No
Sterile	No	Yes	NA
Usage time	5h	72 h	5h
Patient contact	Skin	Intravascular access	No

Summary of Testing:

Verification testing has been performed to verify that the Redsense device fulfills the Requirement Specifications.

Clincal testing was conducted at the Departments of Nephrology/Medicine at Eksjö, Halmstad, Hässleholm, Skövde, and Varberg Hospitals in Sweden. Results showed the device functioned successfully in the clinical environment.

Conclusion: Redsense is similar in function and intended use to the vein pressure component of the Fresenius device and has sensing technology that is similar to the Neotrend device. Verification and clinical testing show the Redsense system to be safe and effective for intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 18 2007

Redsense Medical AB
c/o Ms. Constance G. Bundy
Regulatory Consultant
C.G. Bundy Associates, Inc.
6470 Riverview Terrace
FRIDLEY MN 55432

Re: K071013
Trade/Device Name: Redsense
Regulation Number: 21 CFR §876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: ODX
Dated: October 16, 2007
Received: October 17, 2007

Dear Ms. Bundy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071013

Device Name: Redsense

Indications For Use:

The Redsense device is intended to monitor for potential blood loss from the hemodialysis access site in hemodialysis patients undergoing continuous hemodialysis treatment up to 5 hours in the clinical setting. The device includes a blood sensor incorporated into an adhesive sensor patch. The sensor monitors potential blood leakage from the venous needle puncture site via an infrared light and will alarm if blood leakage is detected via absorption onto the device's sensor patch.

Prescription Use ___X____ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K071013